Individual Safety Report

3356789-6-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting
alth professionals of adverse
nts and product problems

CDER

CDER

FDA Use Only
Triage unit sequence #
110249

A Patient Information

1. Patient Identifier	2. Age at time of event: 38 or Date of birth:	3. Sex	4. Weight
864 In Confidence		☒ female ☐ male	0 lbs or 0 kgs

B Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product Problem

2. Outcomes attributed to adverse event (Check all that apply)
- ☐ death (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization - initial or prolonge
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☒ other: Potential Morbidity

3. Date of event: 9/19/1999 (mo/day/yr)

4. Date of this report: 9/23/1999 (mo/day/yr)

5. Describe event or problem

Patient was taking APAP chronically for post ETOH headache, amounts totaling >3-4Gms/day on a q2 hr basis. Patient also admits to drinking during this period of thime. Patient with 37 random APAP lvl. AST>19000, ALT>5700, and pt/ptt in toxic range. INR initially >6.7.

6. Relevant tests/laboratory data, including dates

AST ALT PT/PTT, INR see text.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

ETOH hx.

C Suspect medication(s)

1. Name (give labeled strength and mfr/labeler, if known)
#1 Acetaminophen/ ETOH ALCOHOL JW
#2

2. Dose, frequency, and route used
#1 prn (taking 650-100mg po q2h)
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimat)
#1
#2

4. Diagnosis for use (Indication)
#1 Headache post hangover
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ N/A
#2 ☐ yes ☐ no ☐ N/A

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ N/A
#2 ☐ yes ☐ no ☐ N/A

9. NDC Number (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name:

2. Type of device

3. Manufacturer name and address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other:

6. RECD.
model #
catalog #
serial #
lot #
other # MEDWATCH CTU

5. Expiration date (mo/day/yr)

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E Reporter (see confidentiality section)

1. Name -address [redacted] Pharmacy [redacted] phone # [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. X

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

DSS

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

SEP 27 1999

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM
HF-2

ADVERSE EVENT REPORTING SYSTEM

CTU 110249